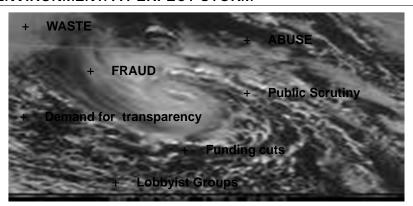






EXTERNAL ENVIRONMENT: A PERFECT STORM



FEDERAL GUIDANCE

+ **Uniform Guidance Objective:** Reduce administrative burdens <u>and</u> risk of waste, fraud and abuse.

What does this mean?

- The Uniform Guidance focuses on the standards the government needs to set to ensure federal awards receive the right level of federal oversight and that waste, fraud and abuse are mitigated.
- Institutions have the **flexibility** to build their own programs to ensure compliance without hindering other institutional objectives (such as growth in research and service to investigators).

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THE COMPLIANCE SPECTRUM

SCIENTIFIC COMMUNITY RESPONSE

+ National Academy of Sciences: Study on administrative burdens.

RESULTS: Need greater balance with regulations

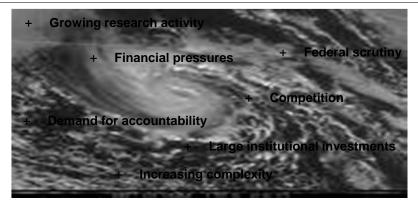
- Well-intended efforts often result in unintended consequences that needlessly encumber the nation's investment in research.
- Some research institutions have failed to respond appropriately to investigators' transgressions or failed to effectively use the tools available.
- No formal, bi-partisan entity exists to consider the effectiveness of existing research policies and review proposed new policies needed to sustain a maximally dynamic, efficient, and effective research enterprise.

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Source: National Academies of Sciences, Engineering, and Medicine. 2015.

Optimizing the Nation's Investment in Academic Research: A New Regulatory
Framework for the 21st Century. Washington, DC: The National Academies Pres

INSTITUTIONAL ENVIRONMENT: A MORE PERFECT STORM



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THE COMPLIANCE SPECTRUM

INSTITUTIONAL RESPONSE: FLEXIBILITY = CHOICE

+ Define the optimal institutional stance on the compliance spectrum

Left: "Soft" Compliance

- More ad hoc decision making and enforcement; less structure
- (Possibly) Greater efficiency
- Less administrative time and effort
- (Possibly) Greater risk

Right: "Hard" Compliance

- Less independent judgement calls
- Added structure; perhaps more 'layers'
- More administrative oversight (and time and effort)
- · Less upfront audit risk (maybe)

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WHY "GO LEFT"?

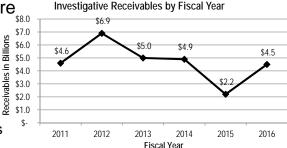
- + Strong customer service (i.e. doing what a PI wants) can conflict with a harder compliance environment
 - The institution may default to the left when there is a lack of clear guidance or empowerment of individuals to take a stand
- + The institutional cost of a more 'soft' compliance structure can be less, e.g. fewer resources are required to maintain a lesser degree of administrative oversight

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THE COMPLIANCE SPECTRUM

WHY "GO RIGHT"?

- + Financial and reputational impacts are significant and increasing
 - FY16 HHS OIG financial penalties resulting from federal audits and investigations of all HHS programs:
 - \$1.2 billion in audit receivables
 - \$4.5 billion in investigative receivables



- + FY2016: 844 criminal actions against individuals/entities; 708 civil actions
- + Institutions may default right -on paper- to mitigate non-compliance fallout

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Source: Department of Health and Human Services Office of the Inspector General Work Plans FY2012 – FY2017

THE CHALLENGES: EITHER WAY

- + PIs and administrators may 'work around' hard compliance (e.g. difficult processes) to find another (riskier?) way
 - Do your PIs ever escalate (straight to the VPR) to overrule any policy, procedure or judgement?
 - Department administrators may be faced with a 'conflict of interest' and go with who pays the bills (usually the PI/Department)
- + Detailed processes can increase audit risk harder to follow your policy
- + Too many approval steps can mean no one really worries about it everyone assume someone else will look at it

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THE COMPLIANCE SPECTRUM

THE CHALLENGES: EITHER WAY

- + Can't see the forest for the trees: Too much focus on detailed processes can lead people to not think about the bigger compliance picture, or the need to make judgment calls
- + Hard compliance can be perceived as poor service and a roadblock to getting good research done

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THE CHALLENGES: EITHER WAY

- + Soft compliance can result in disconnected compliance
 - Administrators may be overly independent
 - No one may have any ownership for compliance
- + Decision making and priority setting may appear inconsistent, and lead to even more challenges
 - Why can that PI do it and not me?



A BALANCED SOLUTION THE IDEAL STATE: HOW DO YOU GET THERE? Cost Service Efficiency Compliance Are you striking the right balance?

A BALANCED SOLUTION

THE IDEAL STATE: EFFECTIVE COMPLIANCE



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+ Effectively provide <u>reasonable assurance</u> that compliance with Federal (and all sponsor type) statutes, regulations, and the terms and conditions of awards will be achieved.

Compliance

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A BALANCED SOLUTION

THE IDEAL STATE: COST & EFFICIENCY CONSIDERATIONS



- Often hand-in-hand considerations
- Benefits to the relative risk should outweigh the qualitative and quantitative costs
- + OMB Compliance Supplement specifically speaks to the fact that too many controls (too much hard compliance) can result in inefficient and ineffective operations



Efficiency

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A BALANCED SOLUTION

THE IDEAL STATE: STRONG SERVICE ELEMENT



- + Keeping the focus of getting good research done
- + Good service can make it easier to follow 'harder' compliance
- Service is the greatest factor in driving investigator satisfaction
- + Direct linkage to creativity in solution development:
 - We can't do that, but based on what you are trying to accomplish, would this work...



CULTURE & MISSION

STRATEGIC ALIGNMENT OF PRIORITIES

- + Build an overall research strategy clear and transparent establishing goals and priorities
 - Provide unifying direction driving the approach to decision-making, investments and prioritization
 - Enable transparency in policy, assessment and decision making
 - Facilitate messaging to the broader research community to support and justify investments or other 'perceived' inequities

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CULTURE & MISSION

TOP-DOWN TONE OF COMPLIANCE

- + Establish a Compliance "Ethos" at the highest level
 - Reinforce the compliance values and consistently act within those boundaries
 - Hold all researchers to the same standards and rules with no special exceptions outside the chain of command
 - Make compliance a shared responsibility
 - Remove the 'conflict of interest'

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CULTURE & MISSION

TOP-DOWN TONE OF COMPLIANCE

- + Establish a Compliance "Ethos" at the highest level
 - Maintain a culture of accountability
 - A lack of *individual accountability* can result in extra layers (hoops!) of processes, approvals, etc.
 - Even MORE audit risk!
 - 'Punishing' the majority for lack of compliance by the few
 - Optimize for those who WANT to do the right thing and need guidance
 - Versus those who don't care

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CULTURE & MISSION

BALANCED LOCAL MISSION

- + Establish your organizational mission incorporating both service and compliance elements
 - Central Research Administration and Department Business Offices
 - Position research offices as customer centric units with a compliance responsibility

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CULTURE & MISSION

EXCELLENCE CLIENT SERVICE

- + Define what "excellence" means
- + Determine what your researchers and investigators value
- + Train service providers and focus on skill sets to achieve the goal
- + Share knowledge
- + Practice patience
- + Prepare for breakdowns

Excellence in Client Service, as a cultural cornerstone, translates directly to achieving researcher satisfaction – *in conjunction with compliance*.

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STRUCTURE & RESOURCES

EMPOWER AND ENTRUST EXECUTION

- + Establish Roles and Responsibilities delineating tasks and authority across functional lines
 - Enable the research community to enact the compliance culture within their realm of responsibility and authority
 - Clear processes and roles and responsibilities make it easier for people to do the right thing
 - Formally include service to a broad range of customers as a component of administrators' roles and responsibilities

STRUCTURE & RESOURCES

EMPOWER AND ENTRUST EXECUTION

- + Recognize how much of the service element is staff attitude
 - Drive to exceed service minimums
 - "Go the extra mile" to provide service to your community
 - Prioritize researcher satisfaction even if the answer to their request is "NO"

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STRUCTURE & RESOURCES

ENABLING TOOLS

- + Provide research compliance management reports and analytic tools
 - Enhance understanding of the current state
 - Focus research compliance efforts
 - Facilitate accountability of PIs and Administrators
 - Allow PIs and Administrators to manage research timely (which can affect cost transfers, effort reports, sub-recipient monitoring, etc.)

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STRUCTURE & RESOURCES

ENABLING TOOLS

- + Develop a broad compliance communications strategy
 - Identify the right channels and communicators for different types of messages
 - Leverage other faculty/leadership (i.e. Deans/Chairs) in delivering messages
 - Maintain brevity

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STRUCTURE & RESOURCES

ENABLING TOOLS

- + Centrally develop and conduct training
 - Utilize different delivery mediums and techniques
 - Focus on key principles, policy and baseline knowledge
 - Don't get too bogged down in the weeds!
 - Provide on-demand, as-needed train to those who need the information, when they need the information

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APPLICATION

WALK THE WALK

- + Bring culture, mission, structure and resources together to support research through both enhanced service and compliance
 - It is not enough to say you are working to achieve researcher satisfaction, if you do not follow through
 - Consistency in service delivery is critical
 - All employees and all customers must be held to the same standard.
 - Incorporate customer service rating part of annual review and/or performance metrics

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APPLICATION

HOW CAN YOU BALANCE IT ALL?

- + How do you build and cultivate relationships with PIs and department and local administrators?
- + What are some of the ways you provide outreach to your customers?
- + What are key messages you give to PIs when they have difficult compliance questions?
- + What are the resources you use?

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APPLICATION

DEVELOP THE SKILLS

- + Focus on the required skill-set for administrators (central and local):
 - Teamwork
 - Effective communication
 - Identifying solutions during complex matters
 - Decision-making
 - Customer service focus
 - Interpersonal skills

It goes FAR beyond understanding the regulations and policies....

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APPLICATION

BACK TO BALANCE



Too much "hard compliance" can result in inefficient operations and feel like poor service.



Strength of compliance and service should be balanced with the relative risk.



The benefits of compliance controls should outweigh the costs.

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CONTACT INFORMATION

MATTHEW STAMAN

Managing Director (312) 804-8475 mstaman@huronconsultinggroup.com

ANNE PIFER

Senior Director (312) 880-3083 apifer@huronconsultinggroup.com

MARISA ZUSKAR

Director (312) 880-3393 mzuskar@huronconsultinggroup.com

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